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beginning at page 11, line 13, has been amended herein to correct this matter. The drawings as filed fully support the recitation of a "partially oval shape" and therefore it is submitted that no new matter has been added. Withdrawal of the objection to the specification is respectfully requested.

Rejections to the claims

Claims 1, 6, 8 and 9 were rejected under 35 USC 102(e) as being anticipated by US Patent 6,033,383 (Ginsburg '383). Claims 2 and 7 were rejected under 35 USC 103(a) as being unpatentable over Ginsburg in view of US Patent 5,624,392 (Saab) and Claims 3-5 were rejected as being unpatentable over Ginsburg in view of US Patent 5,899,899 (Arless et al.).

Specifically, the 102(e) rejection based on Ginsburg states that "Ginsburg discloses a method and apparatus for causing hypothermia...[and] a coaxial catheter (figure 3) with a heat transfer element at its distal tip, inserting the catheter through the vascular system and cooling blood flowing in that portion of the vascular system which also cools the organ associated with that vessel being cooled (col. 4, lines 5-13)".

With regard to Claims 2 and 7, the Action states that "Ginsburg teaches all of the limitations of the claims *except insulating the supply tube*" and then relies upon Saab as teaching "to insulate the supply lumen to prevent cooling of tissue not intended for treatment located in close proximity to the device".

And finally, with respect to Claims 3-5 the Action states that "Ginsburg teaches all of the limitations of the claims *except the heat transfer element being metallic*" and then relies upon Arless as teaching "a metallic heat transfer element that enhances the heat transfer rate of the device"...and states that "it would be obvious...to provide a metallic heat transfer element on the Ginsburg device".

Each of the outstanding rejections is respectfully traversed and reconsideration is requested.

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CLAIMS 1 and 2

Independent Claim 1 is directed to a method for causing hypothermia. A circulating fluid apparatus having a chiller and a flexible catheter is provided, the catheter having an inner lumen and a hollow flexible heat transfer element adjacent its distal tip. The catheter is inserted through the vascular system of a patient to place the heat transfer element in a portion of the vasculature, chilled fluid is supplied to the inner lumen of the catheter and the interior of the heat transfer element is cooled with the chilled fluid. Blood flowing in the portion of the vasculature is cooled with the heat transfer element and the fluid is returned to the chiller. Independent Claim 2 recites that the catheter is coaxial, that the inner lumen is insulated and that the chilled fluid is perfluorocarbon.

Ginsburg is directed to a temperature regulating catheter in which a "liquid medium is introduced into a lumen... [and is] altered while passing through the temperature altering region" (see Abstract) so that it may be "delivered to the target location while the fluid is within the patient" (col. 1, lines 9-11). Ginsburg is silent as to how a chilled fluid is supplied to the catheter and also as to how the chilled fluid exits from any of the catheter embodiments illustrated therein.

* fluid supply

With regard to each of independent Claims 1 and 2, Applicants respectfully submit that Ginsburg, in Figures 1-9, fails to teach or suggest even a *circulating apparatus that operates to cool blood flowing outside the heat transfer element in a vessel*, and moreover, in *all* of the figures fails to teach or suggest a *circulating fluid apparatus* having a "chiller" that supplies chilled fluid to an inner lumen of the apparatus, the fluid then being "returned to the chiller" after cooling the heat transfer element. The references simply do not suggest that any of the embodiments disclosed are "circulating" devices in which fluid from a chiller is circulated through a heat transfer element and returned to the chiller.

For all of the foregoing reasons, each of independent Claims 1 and 2 is believed to be clearly patentable over Ginsburg and over any permissible combination of Ginsburg and Saab.

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CLAIMS 3-5

Independent Claim 3 is directed to a method for selective organ hypothermia of providing a coaxial catheter having an insulated inner lumen and a metallic heat transfer element, introducing the catheter into the vascular system of a patient to place the metallic heat transfer element in a feeding artery of an organ of the patient, cooling the metallic heat transfer element by circulating a refrigerant through the insulated inner lumen of the coaxial catheter, cooling blood in the feeding artery by contact with the cooled metallic heat transfer element and cooling the organ by flow of the cooled blood through the feeding artery. Independent Claim 4 is directed to a method for selective brain hypothermia and Claim 5 is directed to a method for selective hypothermia of the heart, and each recites similar method steps to those of Claim 3 but recites that the coaxial catheter and heat transfer element are flexible.

Applicants respectfully traverse the assertion in the office action that "it would be obvious...to provide a metallic heat transfer element (allegedly taught by Arless) in the Ginsburg device".

Figures 1-9 and the corresponding description of those figures of Ginsburg, are directed to a system in which fluid is *delivered to a specific target location within a body structure* and the temperature of that fluid is altered while passing through the lumen and is then exits the distal end of the catheter into the body. Therefore, each of these embodiments is "designed to optimize the rate of heat transfer between the catheter and a fluid flowing through the internal lumen" (col. 5, lines 61-63) and is not only not concerned with altering the temperature of blood *flowing in a portion of the vasculature...past a heat transfer element*, but in fact Ginsburg expressly states that "the temperature altering mechanism 18 will preferably be arranged within catheter 12 so that the temperature of the luminal wall may be heated or cooled *without substantial direct heating of an outer surface of the catheter 12*" (col.6, lines 6-9). Therefore Figures 1-9 of Ginsburg teach away from combining with any teachings of a device using a *metallic* heat transfer element. ✕

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Unlike the other figures of Ginsburg, Figure 11 shows a system with an in-flow lumen and an out-flow lumen, the heat transfer region 162 in the form of a balloon 170. Applicants submit that a "balloon" heat transfer element appears to *teach away from* any indication of the heat transfer element being *metallic*. The embodiment of Figure 11 merely describes the desire for increased surface area through which heat transfer may take place. Again there is absolutely no teaching or suggestion in Ginsburg to implement a *metallic* heat transfer element into the device illustrated "to enhance the heat transfer rate of the device".

Of course "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination" i.e., "the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Laskowski*, 10USPQ2d 1397, 1399 (Fed. Cir. 1989).

In this regard, the Federal Circuit has repeatedly warned that the requisite motivation must come from the prior art and *not Applicants' specification*. *In re Dow Chem. Co.*, 5 USPQ2d 1529, 1531-32 (Fed. Cir. 1988). Here, although the Examiner provides an argument as to why the modification/combination would be helpful, the Ginsburg and Arless references, at least, plainly fail to suggest the claimed combination.

For all of the foregoing reasons, each of independent Claims 3-5 is believed to be clearly patentable over Ginsburg and Arless taken in any permissible combination.

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CLAIMS 6-9

Claim 6 is directed to an apparatus for selective organ hypothermia including a circulating unit adapted for chilling and circulating a fluid, a flexible elongated catheter, a flexible tubular outer catheter body on the catheter, a flexible fluid supply tube within the outer catheter body, a proximal end of a central lumen of the fluid supply tube being connected in fluid flow communication with an outlet of the circulating unit, a fluid return lumen within the outer catheter body, a proximal end of the fluid return lumen being connected in fluid flow communication with an inlet of the circulating unit and a flexible heat transfer element mounted to a distal end of the outer catheter body, the heat transfer element having a partially helical shape to increase the surface area available for heat transfer. Claim 7 recites the elements of Claim 6 and also recites that the return lumen "substantially surrounds the fluid supply tube" and Claims 8 and 9 recite that the heat transfer element has an at least partially "ballooned" shape and "oval" shape, respectively.

Applicants respectfully submit that Ginsburg fails to teach or suggest the recited "circulating unit adapted for chilling and circulating a fluid" – and therefore Ginsburg cannot teach or suggest an apparatus in which a "proximal end of a central lumen of a fluid supply tube is connected in fluid flow communication with an outlet of the circulating unit" or a "a proximal end of a return lumen connected in flow communication with an inlet of a circulating unit".

In addition, with regard to Claims 6 and 7, Ginsburg and Saab fail to teach or suggest a heat transfer element having a *helical shape*, and with regard to Claim 9, Ginsburg fails to teach or suggest a heat transfer element having an *oval shape*.

Finally, again with regard to Claim 7, Ginsburg and Saab provide no teaching or suggestion of an apparatus in which a "return lumen substantially surrounds a fluid supply tube". Rather, the "out-flow lumen 164" of Ginsburg runs alongside the in-flow lumen 160 (Figure 11) and the "second fluid path 34" also runs alongside "first fluid path 32" (Figure 3). The "return" lumens of Ginsburg do not "substantially surround" a fluid supply tube.

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For all of the foregoing reasons, independent Claims 6, 8 and 9 are believed to be clearly patentable over Ginsburg, and Claim 7 is believed clearly patentable over Ginsburg and Saab taken in any permissible combination.

Since the Applicants have fully responded to each rejection set out in the Office Action, it is respectfully submitted that in regard to the above remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,


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